REMARKS

The Office Action mailed January 25, 2006, has been received and reviewed. Claims 25, 39, 41-45, 74, 83, and 92-115 were previously pending in this application. In the Office Action, Claims 92, 93, 104, 107, 110 and 113 were allowed; Claims 25, 29, 41-45, 74, 83 and 96-103 were rejected; and Claims 94, 95, 105, 106, 108, 109, 111, 112, 114 and 115 were objected to. By the present amendment, Claims 25, 41, 42, and 96-103 have been amended. Thus, Claims 25, 29, 41-45, 74, 83, and 92-115 are currently pending. No new matter is introduced. Favorable reconsideration of the claims is respectfully requested.

The Amendments to the Claims:

Claim 25 has been amended to recite the antigen "induces" a protective immune response against Chlamydia psittaci and "wherein the immune response protects against Chlamydia psittaci-induced disease and accelerates elimination of the Chlamydia psittaci bacteria from an infected animal, and wherein the amount effective is at least a nine-amino acid fragment of the SEQ ID NO:7." Support for this amendment is presented in the Examples within the patent application as filed. The approach to identification of the protective genes is described on Pages 64-80 in Examples 1-6, and illustrated in Figures 1-6. The claims for fragments, full-length DNA and polypeptide sequences of the protective genes are based on the identification of protective DNA fragments of these Chlamydia psittaci genes in the approach outlined in the above examples. Further, evidence for the mouse-protective effect is presented in Figures 5 and 6 for SEQ ID NO:6 (SEQ ID NO:6 is CP4#1), which is the DNA fragment corresponding to claimed polypeptide SEQ ID NO:7. Table 2 of all original protective clones on Page 74 lists the corresponding chlamydial genes. All sequence identification numbers (SEQ ID NO) of clones containing protective gene fragments or the corresponding polypeptides, the full-length protective genes, and the corresponding polypeptides are shown in Table 3 on Pages 75-79.

Claim 41 has been amended to include the limitation "wherein the second Chlamydia psittaci antigen has the effect of increasing the protective capacity against Chlamydia psittaci-induced disease and accelerating the elimination of the Chlamydia psittaci bacteria from an infected animal." Evidence for the enhanced protective effect of combining the DNA sequence (SEQ ID NO:6) corresponding to SEQ ID NO:7 (polypeptide) with a second Chlamydia psittaci antigen is specifically shown in Figure 5 [pool (> 50 AA)].

Claim 42 has been amended to recite that the second Chlamydia psittaci antigen "is at least a nine amino acid fragment." Support for this limitation can be found in the Examples cited above with respect to the remarks in support of Claims 25 and 41 as amended.

Claims 96-103 have been amended to recite that the variant is "a nine-amino acid fragment of a homologous sequence" to a SEQ ID NO and induces a "protective" immune response "against" Chlamydia psittaci, and that "the immune response protects against Chlamydia psittaci-induced disease, and accelerates elimination of the Chlamydia psittaci bacteria from an infected animal." Evidence for the mouse-protective effect of the DNA sequences of gene fragments SEQ ID NO:10, 14, 20, and 24 is shown in Figures 5 and 6 (SEQ ID NO:10 is CP4#2, SEQ ID NO:14 is CP4#3, SEQ ID NO:20 is CP4#4, and SEQ ID NO:24 is CP4#5). These are the DNA fragments corresponding to polypeptide SEQ ID NO:11, 15, 21, and 25, respectively. No new matter has been added by way of these amendments.

Objections to Claims 94 and 95:

Claims 94 and 95 were objected to "as being of improper dependent form for failing to further limit the subject matter of a previous claim." Claims 94 and 95 include a second Chlamydia antigen corresponding to a particular SEQ ID NO. The Applicant is unclear of the reasons behind these objections and request clarification as to the objections of Claims 94 and 95.

Rejections Under Section 112:

In the Office Action, Claims 25, 39, 41-45, 74, 83 and 96-103 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for all antigenic fragments of the SEQ ID NOs. 7, 9, 11 or 13 encompassed by the claims that can be used in the claimed method. Specifically, it is stated that "the specification does not enable any person skilled in the art to which it pertains, or with which it is nearly connected, to make and use the invention in scope with these claims." This rejection is traversed for the reasons set forth below.

The Office alleges that the "specification provides no guidance as how one would begin to choose all 'antigenic fragments' of SEQ ID NOs. 7, 9, 11 or 13 encompassed by the claims...because the specification allegedly does not disclose: the general tolerance to modification and extent of such tolerance; specific positions and regions of sequence(s) which can be predictably modified and which regions are critical; what fragments, if any, can be made which retain the biological activity of the intact protein; and the specification provide essentially no guidance as to which of the essentially infinite possible choice is likely to be successful." However, the Office Action did indicate that the specification was enabling for Chlamydia psittaci antigens having sequences corresponding to SEQ ID NOs: 7, 9, 11, and 13.

The Office contends that undue experimentation is required for one of ordinary skill in the art to make or use proteins of all antigenic fragments of SEQ ID NOs. 7, 9, 11 or 13. Whether or not experimentation is undue depends on the following factors:

(A) the breadth of the claims;

(B) the nature of the invention;

(C) the level of one of ordinary skill;

(D) the level of predictability in the art;

(E) the amount of direction provided by the inventor;

(F) the existence of working examples; and

(G) the quantity of experimentation needed to make or use the invention based on the content of disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the instant case, the nature of the invention is a method of immunizing an animal comprising administering to the animal a Chlamydia psittaci antigen having a specific SEQ ID NO in an amount effective to induce a protective immune response against Chlamydia psittaci, wherein the immune response protects against Chlamydia psittaci-induced, accelerates the elimination of the Chlamydia psittaci bacteria from an infected animal, and wherein the amount effective is at least a nine-amino acid fragment of a specific SEQ ID NO. The breadth of the claims is primarily influenced by the ability of the antigens to induce a protective immune response and employed in vaccination techniques. The antigens of the claims are limited to at least a nine-amino acid fragment of a specific amino acid sequence (SEQ ID NO 7 or SEQ ID NO 9) and induce a protective immune response against Chlamydia psittaci. The Chlamydia psittaci antigens that do not meet these limitations are not encompassed within the scope of the claims. Therefore, although the scope of all of the claims is not limited to a full length amino acid sequence (SEQ ID NO 7 or SEQ ID NO 9), the breadth of the claims is not without limitations and is fully taught by the specification.

The level of one of ordinary skill is enough to make and use the instant invention without undue experimentation. The method of using isolated antigens for producing an immune response was well-known by the filing date of the instant application (see, e.g., Charles A. Janeway, Jr. et al., Immunobiology 105-117 (5th ed. 2001)). The recognition of antigenic epitopes presented by molecules of the Major Histocompatibility Complex (MHC) plays a central role in the establishment, maintenance and execution of mammalian immune responses. The ability of a particular peptide fragment to function as a T cell epitope requires that it bind effectively to the antigen presenting domain of an MHC molecule and also that it display an appropriate set of amino acids that can be specifically recognized by a T cell receptor (TCR) molecule. When the TCR on the surface of the T

cell specifically binds the peptide, the T cell is "activated" and begins to produce one or more cytokines, and thereby inducing an effective cellular immune response against the antigen or antigens being presented, resulting in the elimination of infectious organisms such as Chlamydia psittaci. The art of making and using antigenic peptides is also well known using PCR techniques for amplifying a coding sequence of the DNA of a fragment, cloning these into expression vectors, expressing the protein in any recombinant protein expression system and then purifying as recombinant protein. Any person skilled in the art can do this.

Working examples are found in the instant specification. The present specification demonstrates that the 443 amino acid polypeptide of SEQ ID NO: 9 and the 100 amino acid polypeptide of SEQ ID NO: 13 can be used to immunize an animal. The specification also demonstrates that a 149 amino acid fragment (SEQ ID NO: 7) of SEQ ID NO: 9 and a 41 amino acid fragment (SEQ ID NO: 11) of SEQ ID NO: 13 can be used to immunize an animal. Identification of the protective genes is described on pages 64-80 in Examples 1-6, and illustrated in Figures 1-6. The claims for fragments and full-length DNA and polypeptide sequences of the protective genes are based on the identification of protective DNA fragments of the Chlamydia psittaci genes in the approach outlined in the above examples. Specific evidence for the mouse-protective effect is presented in Figures 5 and 6 for SEQ ID NO:6 (SEQ ID NO:6 is CP4#1), which is the DNA fragment corresponding to claimed polypeptide SEQ ID NO:7. Table 2 of the original protective clones on page 74 lists the corresponding chlamydial genes. All sequence identification numbers of (SEQ ID NO) of clones containing protective gene fragments or the corresponding polypeptides, and the full length protective genes and the corresponding polypeptides are shown in Table 3 on pages 75-79. Evidence for the enhanced protective effect of combining the DNA sequence (SEQ ID NO:6) corresponding to SEQ ID NO:7 (polypeptide) with a second Chlamydia psittaci antigen is specifically shown in Figure 5 [pool (> 50 AA)]. Also, specific evidence for the mouse-protective effect of the DNA sequences of gene fragments SEQ ID NOs: 10, 14, 20, and 24 is shown in Figures 5 and 6 (SEQ ID NO:10 is CP4#2, SEQ ID NO:14 is CP4#3, SEQ ID NO:20 is CP4#4, and SEQ ID

NO:24 is CP4#5). These are the DNA fragments corresponding to polypeptide SEQ ID NOs:11, 15, 21, and 25, respectively.

One of ordinary skill in the art could simply make and use these at least nine-amino acid antigens and antigenic fragments that are taught by the specification, as well as other antigenic fragments of SEQ ID NOs: 9, 13, 7 and 11 and thereby induce a protective immune response, by following the teachings of the art and the specification. Even an extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance. *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). Thus, the instant specification provides an ample amount of direction to one of ordinary skill.

The Office Action alleges that the specification does not disclose "the general tolerance to modification and extent of such tolerance; specific positions and regions of sequences which can be predictably modified and which regions are critical; and what fragments, if any, can be made which retain the biological activity of the intact protein...and whether the fragments retain the desired functional effects." Applicants submit that functionality of the protein is random, and is variable for each individual. For example, different sets of 9-28-mer polypeptides of the claimed protective proteins of the present invention may induce protective immunity in different individuals. One cannot discern which fragment will be presented in an individual by simply taking a biochemical view of the problem. That said, the present invention is directed to making and using polypeptides, and it is the peptide fragments of these polypeptides, generated differently by each individual, that elicit protective immunity, and thus are important to practicing the claimed methods of the present invention. Furthermore, out of the approximately 1,050 immunogenic, but not necessarily protective, proteins encoded in the C. psittaci genome, the Applicants have identified the exact sequence ID NOs. that elicit a protective immune response.

In view of the breadth of the claims, the nature of the invention, the working examples disclosed in the instant specification, the amount of direction provided by the inventor, the level of the ordinary skilled artisan, undue experimentation would not be required by one of ordinary skill in

the art to make or use the at least nine-amino acid variants or fragments of SEQ ID NOs: 7, 9, 11 and 13 in the context of inducing an immune response against Chlamydia psittaci.

Rejections Under 35 U.S.C. § 102

The Office Action maintains the rejection of Claims 25, 39, 41-45, 74, 83 and 100-103 under § 102(e) as being anticipated by Griffais et al. (U.S. Patent No. 6,559,294). The Action also rejects the same claims under § 102(b) as being anticipated by Griffais et al. (WO 99/27105). As mentioned in this prosecution, the disclosures of U.S. Patent No. 6,559,294 and WO 99/27105 are the same and for convenience, Applicants will refer to the publications collectively as "Griffais". Applicants respectfully traverse the rejections.

Applicants have determined that identifying suitable Chlamydia psittaci sequences for use as a vaccine is no easy matter. Applicants have figured out which of the approximately 1,050 Chlamydia psittaci proteins work as effective immunogens, which requires identifying sequences that generate this protective immune response. In short, Applicants have identified the gene product Chlamydia cannot "hide" from the immune response of the infected individual despite the fact that these gene products elicit an immune response that is unfavorable for the chlamydia bacteria because they allow the host to eliminate chlamydia.

Griffais' contribution is the sequence of the C. pneumoniae genome. In contrast to the present invention, Griffais does not provide vaccines or useful teachings as to how to obtain them. Griffais offers no more than standard vaccine methodology. The instantly claimed at least nine-amino acid fragments and variants of the present invention are not the invention patented in Griffais. That patent contains only claims to polynucleotides comprising certain open reading frames (ORFs) from the Chlamydia pneumoniae genome and methods for expressing a protein from such ORFs. There are no claims to vaccines or to use of such ORFs in making vaccines, let alone specific guidance concerning antigenic fragments of SEQ ID NOs 7, 9, 11 or 13.

The Office Action identifies certain homologs of C. pneumoniae that correspond to peptides claimed in the present invention. However, since such homologies are to be expected among highly related bacteria, these sequences do not imply protective capacity simply by virtue of their existence. Griffais have in no way shown the protective capacity of the C. pneumoniae homologs, and thus their work does not anticipate fragments claimed in the present invention.

Withdrawal of the rejection under 35 U.S.C. § 102 in view of Griffais is requested.

CONCLUSION

In view of the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, Applicant earnestly solicits early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone Applicant's undersigned attorney at (334) 844-4977.

Respectfully submitted,

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STATEMENT OF SUBSTANCE OF INTERVIEW

A personal interview was conducted April 11, 2006 by the Examiner, inventor Bernhard Kaltenboeck, and applicants' undersigned representative. The Interview Summary prepared by the Examiner provides a complete and accurate record of the interview, and addresses the matters indicated in M.P.E.P. § 713.04.